

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, drawn to a method for molding contact lens.

Group II, claim(s) 8-21, drawn to an apparatus used for molding contact lens.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The technical features which are common to both sets of claims are the use of two stage mold which compresses the raw material at two different stages in order to utilize a raw material reservoir to compensate for contact shrinkage in a mold. These technical features are taught by Sealy (GB 22307320—Made of Record by the Applicant) at page 3, lines 29-37. Sealy describes the use of a force to compress the mold from a primary limit to an essential limit (i.e. first position to a second position). Therefore since the limitations of Groups I and II fail to define a contribution over Sealy they fail to constitute a special technical feature and hence there is lack of unity between the cited groups of claims. Moreover, Group II includes the use of a ram means not seen in group I.

3. During a telephone conversation with Chad Hinrichs on November 19, 2008 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-7. Affirmation of this election must be made by applicant in replying to this Office action. Claims 8-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. **Applicant has cited many patent documents in specification that are not listed on an IDS. See for example, US 4113224 and 4197266 on page 2 line 11 of applicant's specification and EP 038425 on page 2 line 26.**

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Hagmann et al. (USP No. 6,800,225).

7. Regarding claim 1, Hagmann discloses a method of moulding a contact lens using a male mould and a female mould, the method comprising the steps of:

- a. (a) introducing lens-forming material in a liquid state into the female mould; **(See column 6 lines 14-21—disclosing that a uncrosslinked liquid**

starting material which is to be used for making contact lens is added to the female mold half)

- b. (b) inserting the male mould into the female mould to a first relative position to form an assembly of the male and female moulds in which the moulds together define a moulding cavity and a reservoir for lens-forming material; **(See column 6 lines 22-38 and column 4 lines 14-29—disclosing that the two mould halves [male and female mold] are closed and thus leaving an annular gap between the two mold halves. In sum, the molds are contacted to a first relative position in which a gap is defined and contained by spacers. See Figure 1 (part # 19a) which shows the spacer that holds the molds together.)**
- c. (c) during the insertion of the male mould to the first position thereof expelling part of the liquid state lens-forming material from the moulding cavity to the reservoir; **(See abstract disclosing that the purpose of the gap is to allow excess material in the mold cavity to be displaced. It is conventional in the art to incorporate a reservoir to work in communication with a gap. See for example, Column 2 lines 15-24-- disclosing that prior art has utilized the gap by connecting the gap to an annular reservoir channel.)**
- d. (d) initiating curing of the lens-forming material in the moulding cavity whilst keeping open a pathway between the moulding cavity and the reservoir so as to allow lens-forming material to flow from the reservoir into the moulding cavity to compensate for shrinkage of the lens-forming material during curing;

(See column 6 line 51-- disclosing that the lens forming material is polymerized or crosslinked. Again it is conventional in the art to polymerize the material while the gap is open and the reservoir still communicates with the gap. See for example, Column 2 lines 15-24-- disclosing that prior art has utilized the gap by connecting the gap to an annular reservoir channel.)

e. (e) applying an external force on the assembly of moulds to insert the male mould further into the female mould to a second position relative to the female mould in which the moulding cavity is closed and sealed off from the reservoir; (See column 4 lines 14-48 disclosing that the male and female mould can be moved two a second position if the spacers that define the gap is altered. Lines 39-42 specifically points to the use of an external closing unit that would apply force or means to close the mold and seal off the gap.)

f. (f) allowing the lens-forming material to complete transformation to a final, glassy solid state within the sealed moulding cavity; and (See column 6 lines 58-63—disclosing that fully polymerized lens are removed from the mold)

g. (g) removing the formed contact lens from the assembly of male and female moulds after the lens-forming material has reached the final glassy solid state thereof. (See column 6 lines 58-63—disclosing that fully polymerized lens are removed from the mold)

i. In sum, Hagmann discloses a process used to mold contact lens which utilizes a dual stage closing process to fully polymerize the contact

material. Hagmann first closes the mold to a first position, defined by a gap between the mold halves which is in communication with an reservoir.

At this point polymerization commences and Hagmann teaches that the gap in the first position can be sealed into a second position during the polymerization process (See column 4 lines 32-38).

8. Regarding claim 4, Hagmann teaches wherein a thickener is added to the lens-forming material to increase the viscosity of the lens-forming material. (See column 10 lines 50-54, column 18 lines 54-57, and column 19 lines 10-18—disclosing that the starting material (lens forming material) must be viscous. Furthermore, Hagmann teaches that polyvinyl alcohol can be added to increase viscosity. The inclusion of polyvinyl alcohol would inherently cause the lens forming material to be viscous. Polyvinyl alcohol is well known in the art as a thickener. See for example US Patent 6,315,410 by Doshi which discloses that polyvinyl alcohol is a known thickener.)

9. Regarding claim 5, Hagmann teaches adding the steps of: forming the male and female moulds by an injection moulding process and using each pair of injection moulded male and female moulds only once in the formation of a single contact lens. (See column 1 lines 54-60-- disclosing that molds are made of plastic (injection molded) and can be disposable.)

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
12. Claims 2 and 6-7 rejected under 35 U.S.C. 103(a) as being unpatentable over Hagmann et al. (USP No. 6,800,225).

13. Regarding claim 2, Hagmann does not specifically teach wherein: the assembly of male and female moulds is heated to initiate curing of the lens-forming material.

(However, Hagmann discloses that the curing of the lens forming material is done by UV Radiation. (See column 6 lines 51-57). It is well known in the art to use a thermal action such as the heating of the mold in order to initiate curing of the lens forming material. For example, Hagmann discloses that a thermal action or non-thermal actions can be used to cure the material. (See Column 1 lines 41-46). Therefore, it would have been obvious to one having the ordinary skill in the art

to substitute the non-thermal curing means used by Hagmann with the thermal mould heating means claimed by applicant in this application.)

14. Regarding claim 6, Hagmann does not specifically teach wherein: a plurality of pairs of male and female moulds are injection moulded; the liquid state lens forming material is deposited in the plurality of female moulds; the plurality of male moulds are inserted into the female moulds, each being inserted to a first position in a respective female mould, to form a plurality of assemblies of male and female moulds; the plurality of male moulds are all simultaneously displaced from the first positions thereof to the second positions thereof. **(It is well known in the art of contact mold production to utilize a system which contains a plurality of pairs of male and female moulds. Hagmann clearly discloses that contact lenses are manufactured in large numbers (See column 1 lines 19-21).)**

h. Furthermore, Hagmann discloses the claimed invention except for the duplication of the system elements (male and female molds as well as dual compression in all molds). It would have been obvious to one having ordinary skill in the art at the time the invention was made to duplicate the system components, since it has been held that mere duplication of essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

15. Regarding claim 7, Hagmann does not specifically teach wherein: the assembly(ies) of moulds is/are placed in a curing oven **(See figure 1 and part numbers 2a and 2b which define an non-thermal energy unit which heats up the**

lens forming material in the mold. The energy source (2a) and the energy means (2b) when acting in concert essentially act as an oven. Furthermore, it is well known in the art to use an heating oven when utilizing thermal energy to heat of the mold. Also see column 1 lines 41-46 disclosing the use of thermal action to fully cure the lens forming material.]; timing means is used to time duration of residence of the moulds in the curing oven; and after a first measured time period the external force is applied to each male mould to move each male mould from the first position thereof to the second position thereof. **(It would have been obvious to one having the ordinary skill in the art at the time of invention to adjust the duration time in the oven for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980.)**

i. Using timing means to determine the adequate time to cook the molds would be obvious to one skilled in the art. It is extremely important for contact lenses to be made consistently within specifications to ensure accuracy and therefore it will always be the case to monitor the duration of the molds in the curing oven.

16. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hagmann et al. (USP No. 6,800,225) in view of Hirota et al (USP No. 5,114,455).

17. Regarding claim 3, Hagmann does not explicitly teach wherein: the male and female moulds are heated at least until the closing of the mould cavity and prior to the closing of the mould cavity the lens-forming material is kept at a temperature above the

glass transition temperature of the lens-forming material; the lens-forming material is cooled below the glass transition temperature in the closed moulding cavity; and removing the formed contact lens from the mould cavity occurs after the lens-forming material has cooled below the glass transition temperature thereof.

- j. However, Hirota discloses wherein:
 - ii. the male and female moulds are heated at least until the closing of the mould cavity and prior to the closing of the mould cavity the lens-forming material is kept at a temperature above the glass transition temperature of the lens-forming material; (See column 1 lines 9-23, disclosing that the contact material and mold is heated prior to closing of mold in order to soften the contact material. It would have been obvious to one having the ordinary skill in the art to heat the material above the glass transition temperature to lower the viscosity and soften the lens forming material.)
 - iii. the lens-forming material is cooled below the glass transition temperature in the closed moulding cavity; and (See column 1 lines 9-23, disclosing that after the mold is press molded the temperature of the lens forming material is lowered to a point below the glass transition temperature of the material.
 - iv. removing the formed contact lens from the mould cavity occurs after the lens-forming material has cooled below the glass transition temperature thereof. (See column 1 lines 9-23, disclosing that after the

**cooling below the glass transition temperature the lens is removed
from the mold portions.)**

k. Hagmann and Hirota are analogous art because they are from the same field of endeavor which is forming optical lenses. At the time of the invention, it would have been obvious to the applicant being one of ordinary skill in the art, having the teachings of Hagmann and Hirota before him or her, to modify the teachings of Hagmann to include the teachings of Hirota because it is well-known in many arts that when casting a lens to first heat up the material to a temperature above the glass transition material so that the material can be easily compressed and formable. Once compression starts the mold in a traditional casting process will be cooled so that the end product is formed. It would have been obvious to use the known step of preheating the mold prior to compression to effectuate a lens casting process.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The reference Bishop et al. (USP No. 6,267,587) which discloses a thermal curing oven and thermal curing process for lens manufacturing. The reference Morland et al. (USP No. 5,114,629) which discloses a process for casting lens.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMJAD ABRAHAM whose telephone number is (571)270-7058. The examiner can normally be reached on Monday through Friday 8:00 AM to 5:00 PM Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Phillip Tucker can be reached on (571) 272-1095. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AAA

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